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510 (k) Summary

Summary of 510 (k) safety and effectiveness information upon which the substantial equivalence determination is based:

Prepared: August 8, 2005

Applicant: Futura Biomedical
990 Park Center Drive, suite H
Vista, CA 92081

Telephone: 760-599-1670
Fax: 760-599-1675
Contact: Louise M. Focht

Device Name:	Smooth or threaded metallic bone fixation fastener
Device Trade Name:	Tapered Compression Pin
Device Classification:	Class II
Reviewing Panel:	Orthopedic
Regulation Number	888.3040
Product Code:	87 JDW
Predicate Device:	K993910
Registration Number:	2030833
Owner Operator Number:	9028319

Device Description:

The Futura Biomedical Implant is a one-piece device made of Stainless Steel or Titanium Alloy, intended for fixation of bone fractures, bone reconstruction, osteotomy or arthrodesis. The implant is designed in 3 sizes. The device is tapered and threaded on the leading end and smooth on the trailing end. The implant is used in the treatment or bone fractures of bone reconstruction, including osteotomy, and joint fusion. The design of the Futura Biomedical Tapered Pin is similar in shape and size to the Newdeal TAC pin. Both devices consist of a tapered, threaded pin that fits into a pin driver. Surgical instruments include a k-wire, drill, pin cutter, pliers, and trephine. No new materials are used in the development of this implant.

Indications for Use:

The Futura Biomedical Tapered Compression Pin is intended to be implanted for the fixation of bone fractures, bone reconstruction, osteotomy or arthrodesis of the foot and ankle and hand and wrist.

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Comparison to Predicate Device:

The legally marketed predicate device to which this device is substantially equivalent is the Newdeal TAC pin.

Regulatory Class: II
Product Code: 87 JDW

Comparison of Futura Biomedical and Newdeal Products

Item	*Futura Product*	*Newdeal Product*
Product Name	Tapered Compression Pin	TAC pin
Use	Single use	Single use
Fixation	Bone	Bone
Material	316L Stainless Steel, ASTM F138 Ti6Al4V, ASTM F136 Titanium Alloy	Ti6Al4V, ASTM F136 Titanium Alloy
Sizes	3 Sizes	3 Sizes
Diameter	2.0, 2.7, 3.0 mm	1.6 mm
Length	overall length 80mm thread length (.59, .79, .98 in)	Overall length 3.75" thread length (15, 20, 25 mm)
Indications for use	The Futura Biomedical Tapered Compression Pin is intended to be implanted for the fixation of bone fractures, bone reconstruction, osteotomy or arthrodesis of the foot and ankle and hand and wrist.	The TAC pin is indicated for synthesis of small bone fragments in the foot only. Examples include: Akin type osteotomy First MP arthrodesis Phalangeal arthrodesis Small bones osteosynthesis requiring compression

Similarities of the Futura Biomedical Tapered Compression Pin and the Newdeal TACpin include:

Both devices are: intended for single use only; intended for surgical implantation longer than 30 days; both devices are placed into bone, for fracture repair, bone reconstruction, osteotomy, or arthrodesis, both devices are threaded, no new materials are introduced in the product; Both devices are comparably sized; both devices have the same indications for use.

Summary:

The device and the predicate device have similar design characteristics and intended use. The new device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 6 2005

Ms. Louise M. Focht
Futura Biomedical
990 Park Center Drive, Suite H
Vista, California 92081

Re: K051740
Trade/Device Name: Tapered Compression Pin
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: JDW
Dated: June 27, 2005
Received: June 28, 2005

Dear Ms. Focht:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0210. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051740
Device Name: Tapered Compression Pin
Indications for Use:

The Futura Biomedical Tapered Compression Pin is intended to be implanted for the fixation of bone fractures, bone reconstruction, osteotomy or arthrodesis of the foot and ankle and hand and wrist.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K051740